

REMARKS

I. Claims in the Case

Claims 4, 6, 12, 19, 25, 30, 40-45 have been amended. Claim 29 has been canceled. Claims 4-10, 12, 19, 22-23, 25 and 30-34 and 38-45 are currently pending and under examination.

The “transduced cell” claims have been amended and are now directed to hematopoietic progenitor cells. Claim 30 has been placed into independent form. Claims 40-45 have been amended to change them to depended claims, depending from claim 39. The remaining amended claims were amended to change their dependencies to conform to the fact that claim 30 is now the base independent claim.

II. Reintroduction of Withdrawn Claims

The Examiner has requested that Applicants cancel the withdrawn claims 11, 20, 21 and 24 in response to the Final Action. However, Applicants note that the new linking claim, independent claim 30, is in condition for allowance as there are no pending prior art rejections as to that claim. Thus, Appellants request reintroduction and examination of the withdrawn claims, as noted in MPEP §809, which states:

The linking claim must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn. Any claim directed to the nonelected invention, previously withdrawn from consideration, which depends from or includes all of the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim, the examiner must notify applicant that any canceled, nonelected claim which depends from or includes all the limitations of the allowable linking claim may be reinstated by submitting the claim in an amendment. Upon entry of the amendment, the amended claim will be fully examined for patentability.

Upon reintroduction, Applicants intend to make each of the withdrawn claims dependent from claim 30, which should place these claims in condition for allowance as well.

III. Provisional Double Patenting

The Action first provisionally rejects various of the claims over various claims of later-filed copending application 10/261,078. In response to this rejection, Applicants note that the '078 application is still pending and no claims have been allowed. Thus, if the present case is in condition for allowance it is appropriate to withdraw the provisional double patenting rejection.

IV. Anticipation Rejection Over Zufferey *et al.*

The Action next rejects claims 4-8, 25, 29 and 40-45 as anticipated by Zufferey *et al.*, with the Action taking the position that Zufferey *et al.* discloses SIN vectors employing a CMV promoter and that CMV promoters are known to be able to at least promote detectable expression in hematopoietic cells.

In response, it is noted that this rejection is now moot with respect to claims 4-8, 25 and 29 in that claim 29 has been canceled and the remaining of these claims now depend from claim 30, in light of the fact that claim 30 was not included in any prior art rejection. Similarly, with respect to claims 40-45, these claims now depend from claim 39, which also was not included in this particular rejection.

V. Rejection of Claims as Obvious Over Zufferey *et al.* in view of Deisseroth *et al.*

The Action next rejects claims 12, 32-34 and 38-39 as obvious over Zufferey *et al.* (1998) in view of Deisseroth, arguing that Zufferey *et al.* teach transfer vectors having the SIN design but does not teach hematopoietic stem cells or other progenitor cells. Deisseroth is said to teach transduction of early hematopoietic progenitor cells using a lentivirus. Thus, the

combination is said to suggest the substitution of the hematopoietic cells of Zufferey *et al.* with the hematopoietic progenitor cells of Deisseroth.

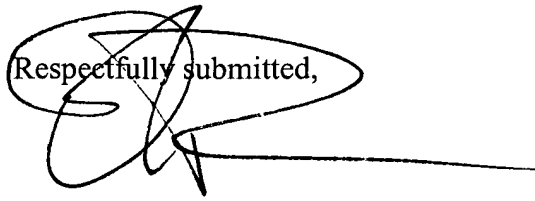
In response, the Applicants contend that the Action failed to set forth a *prima facie* obviousness rejection. It is our position that there is no motivation to combine the teachings of Deisseroth with those of Zufferey *et al.*, in that there was no reasonable expectation that the SIN design would work in hematopoietic progenitor cells. We have been unable to identify any teaching *per se* in Zufferey *et al.* that would suggest employing the SIN design in the context of hematopoietic hematopoietic progenitor cells. If the Examiner is aware of any such teaching she is respectfully requested to point it out. In fact, the SIN design incorporates modifications in their LTR region that reduces their promoter activity, and there was simply no way of knowing in advance what effect this would have on its ability to transfect and express in such cells. The reason for this is that neither the transcriptional *milieu* nor the specificities in hematopoietic progenitor cells have been well characterized. As a consequence, the behavior of internal promoters with respect to the LTR regions in the context of a SIN design could not be predicted in advance. Thus, without having a reasonable expectation that a SIN vector could be successfully employed in hematopoietic progenitor cells, there would be no reason or basis for modifying the SIN-CMV-hematopoietic cell of Zufferey *et al.* to employ a progenitor cell. Furthermore, Zufferey *et al.* not only fails to suggest the applicability of SIN design vectors to hematopoietic progenitor cells, it also appears to be silent as to any drawbacks associated with the CMV promoter in this or any context.

VI. Conclusion

It is submitted that the present case is now in condition for allowance, and a favorable action is earnestly solicited. In this regard, the Examiner is invited to contact the undersigned

attorney at (512) 536-3055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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